

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

DiCICCO-BLOOM, Emanuel et al

Serial No.: 10/044,722

Filed: January 11, 2001

For: PITUITARY ADENYLATE  
CYCLASE-ACTIVATING POLYPEPTIDE  
(PACAP) IS AN ANTI-MITOGENIC  
SIGNAL FOR SELECTED NEURONAL  
PRECURSORS IN VIVO

Group Art Unit: 1645

Examiner: to be assigned

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO-1449 and copies are enclosed for the convenience of the Examiner.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

LA-236727.1

CERTIFICATE OF MAILING  
(37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

June 5, 2002  
Date of Deposit

Melody K. Gutierrez  
Name of Person Mailing Paper  
Melody K. Gutierrez  
Signature of Person Mailing Paper

**INFORMATION DISCLOSURE STATEMENT FILING PROVISION:**

This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d); or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR §1.17(p) or any fees required by this filing to Lyon & Lyon's Deposit Account No. **12-2475**.

Respectfully submitted,  
LYON & LYON LLP

Dated: \_\_\_\_\_

June 5, 2002

By: \_\_\_\_\_

L. Shiger

Lauren Shiger  
Reg. No. 51,086

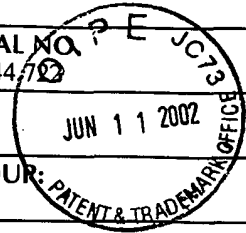


**22249**

PATENT TRADEMARK OFFICE

LYON & LYON LLP  
633 W. Fifth Street, Suite 4700  
Los Angeles, CA 90071  
Phone: (213) 489-1600  
Fax: (213) 955-0440

<b>FORM PTO-1449</b>  <b>LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b>  (Use several sheets if necessary)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"> <b>ATTY. DOCKET NO.</b> 270/175         </td> <td style="width: 50%;"> <b>SERIAL NO.</b> 10/044,792         </td> </tr> <tr> <td colspan="2"> <b>APPLICANT:</b> DiCICCO-BLOOM, Emanuel et al.         </td> </tr> <tr> <td> <b>FILING DATE:</b> January 11, 2001         </td> <td> <b>GROUP:</b> PATENT &amp; TRADEMARK OFFICE         </td> </tr> </table>	<b>ATTY. DOCKET NO.</b> 270/175	<b>SERIAL NO.</b> 10/044,792	<b>APPLICANT:</b> DiCICCO-BLOOM, Emanuel et al.		<b>FILING DATE:</b> January 11, 2001	<b>GROUP:</b> PATENT & TRADEMARK OFFICE
<b>ATTY. DOCKET NO.</b> 270/175	<b>SERIAL NO.</b> 10/044,792						
<b>APPLICANT:</b> DiCICCO-BLOOM, Emanuel et al.							
<b>FILING DATE:</b> January 11, 2001	<b>GROUP:</b> PATENT & TRADEMARK OFFICE						



U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
	AA	5,128,242	7/7/1992	Arimura et al.	435	7.21	6/19/1989
	AB	5,858,787	1/12/1999	Onda et al.	435	471	3/5/1997
	AC	6,017,533	1/25/2000	Moro et al.	424	185.1	4/25/1996

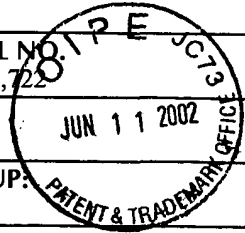
FOREIGN PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES	TRANSLATION NO
	AD							
	AE							
	AF							

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)		
	AG	Antonopoulos et al., "Activation of the GABA <sub>A</sub> receptor inhibits the proliferative effects of bFGF in cortical progenitor cells," Eur. J. Neurosci., Vol. 9, (1997) pp. 291-298
	AH	Arimura, "Perspectives on pituitary adenylate cyclase activating polypeptide (PACAP) in the neuroendocrine, endocrine, and nervous systems," Jpn J Physiol, Vol. 48, (1998) pp. 301-331
	AI	Cacalano et al., "Neutrophil and B cell expansion in mice that lack the murine IL-8 receptor homolog," Science, Vol. 265, (7/29/1994) pp. 682-684
	AJ	Calupca et al., "Origin of Pituitary Adenylate Cyclase-Activating Polypeptide (PACAP)- Immunoreactive Fibers Innervating Guinea Pig Parasympathetic Cardiac Ganglia," J Comparative Neurol Vol. 423 (2000) pp. 26-39
	AK	Carey et al., "Pituitary Adenylate Cyclase Activating Polypeptide Anti-Mitogenic Signaling in Cerebral Cortical Progenitors Is Regulated by p57 <sup>Kip2</sup> - Dependent CDK2 Activity," J Neurosci, Vol. 22, No. 5, (3/1/2002) pp. 1583-1591
	AL	Chatterjee et al., "Molecular cloning of a novel variant of the pituitary adenylate cyclase activating polypeptide (PACAP) receptor that stimulates calcium influx by activation of L-type calcium channels," J. Biol. Chem., Vol. 271, No. 50, (12/13/1996) 32226-32232
	AN	Cole et al., "The EBV-Hybridoma Technique and Its Application to Human Lung Cancer," Monoclonal Antibodies and Cancer Therapy, Alan R. Liss, Inc., New York, NY (1985) pp. 77-96 (1985).
	AO	Creighton, "Proteins: Structure And Molecular Properties," 2nd Ed., W. H. Freeman and Company, New York (1993)
	AP	DiCicco-Bloom et al., "Autocrine expression and ontogenetic functions of the PACAP ligand/receptor system during sympathetic development," Dev. Biol., Vol. 219, (2000) pp. 197-213
	AQ	Drago et al., "Fibroblast growth factor mediated proliferation of central nervous system precursors depends on endogenous production of insulin-like growth factor I," Proc. Natl. Acad. Sci. USA, Vol. 88, (3/1/01991) pp. 2199-2203

LA-231042.1

<b>EXAMINER:</b>	<b>DATE CONSIDERED:</b>
EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant	

<b>FORM PTO-1449</b>  <b>LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b>  (Use several sheets if necessary)	<b>ATTY. DOCKET NO.</b> 270/175	<b>SERIAL NO.</b> 10/044,722
	<b>APPLICANT:</b> DiCICCO-BLOOM, Emanuel et al.	
	<b>FILING DATE:</b> January 11, 2001	<b>GROUP:</b>

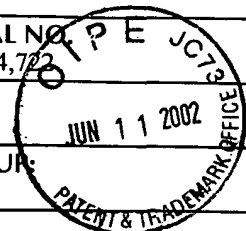


AR	Ghosh et al., "Distinct roles for bFGF and NT-3 in the regulation of cortical neurogenesis," Neuron., Vol. 15, (1995) pp. 89-103
AS	Harlow et al., "Antibodies; A Laboratory Manual," Cold Spring Harbor Laboratory, New York (1988).
AT	Jaworski et al., "Expression of pituitary adenylate cyclase-activating polypeptide (PACAP) and the PACAP-selective receptor in cultured rat astrocytes, human brain tumors, and in response to acute intracranial injury," Cell Tissue Res, Vol. 300, (2000) pp. 219-230
AU	Kimura et al., "A Novel Peptide Which Stimulates Adenylate Cyclase: Molecular Cloning and Characterization of the Ovine and Human cDNAs," Biochem and Biophys Res Commun., Vol. 166, No. 1, (1/15/1990) pp. 81-89
AV	Köhler et al., "Continuous cultures of fused cells secreting antibody of predefined specificity," Nature, Vol. 256, (8/7/1975) pp. 495-497
AW	Kozbor et al., "The production of monoclonal antibodies from human lymphocytes," Immunology Today, Vol. 4, No. 3, (1983) pp. 72-79
AX	LoTurco et al., "GABA and glutamate depolarize cortical progenitor cells and inhibit DNA synthesis," Neuron, Vol. 15, (12/1995) pp. 1287-1298
AY	Lu et al., "Opposing Mitogenic Regulation by PACAP in Sympathetic and Cerebral Cortical Precursors Correlates With Differential Expression of PACAP Receptor (PAC <sub>1</sub> -R) Isoforms," J Neurosci Res, Vol. 53, (1998) pp. 651-662
AZ	Lu et al., "Pituitary adenylate cyclase-activating polypeptide is an autocrine inhibitor of mitosis in cultured cortical precursor cells," Proc. Natl. Acad. Sci. USA, Vol. 94, (4/1997) pp. 3357-3362
BA	McPherron et al., "Regulation of skeletal muscle mass in mice by new TGF- $\beta$ superfamily member," Nature, Vol. 387, (5/1997) pp. 83-90
BB	Miyata et al., "DH: Isolation of a novel 38 residue-hypothalamic polypeptide which stimulates adenylate cyclase in pituitary cells," Biochem. Biophys. Res. Commun., Vol. 164, No. 1, (10/16/1989) pp. 567-74
BC	Moro et al. "Functional characterization of structural alterations in the sequence of the vasodilatory peptide Maxadilan yields a Pituitary Adenylate Cyclase-activating Peptide type 1 receptor-specific antagonist," J. Biol. Chem., Vol. 274, No. 33, (8/13/1999) pp. 23103-23110
BD	Nicot et al., "Regulation of neuroblast mitosis is determined by PACAP receptor isoform expression," Proc. Natl. Acad. Sci. USA, Vol. 98, No. 8, (4/10/2001) pp. 4758-4763
BE	Noctor et al., "Neurons derived from radial glial cells establish radial units in neocortex," Nature, Vol. 409, (2/8/2001) pp. 714-720
BF	Ogi et al., "Molecular Cloning and Characterization of cDNA for the Precursor of Rat Pituitary Adenylate Cyclase Activating Polypeptide (PACAP)," Biochem and Biophys Res Commun, Vol. 173, No. 3, (12/31/1990) pp. 1271-1279
BG	Pellegrini et al., "VIP and PACAP potentiate the action of glutamate on BDNF expression in mouse cortical neurones," Eur. J. Neurosci., Vol. 10, (1998) pp. 272-280
BH	Pisegna et al., "Cloning and Characterization of the Signal Transduction of Four Splice Variants of the Human Pituitary Adenylate Cyclase Activating Polypeptide Receptor," J Biol Chem, Vol. 271, No. 29, (7/19/1996) pp. 17267-17274
BI	Reglodi et al., "Delayed Systemic Administration of PACAP38 Is Neuroprotective in Transient Middle Cerebral Artery Occlusion in the Rat," Stroke, Vol. 31, (6/2000) pp. 1411-1417
BJ	Sheward et al., "Expression of pituitary adenylate cyclase activating polypeptide receptors in the early mouse embryo as assessed by reverse transcription polymerase chain reaction and in situ hybridisation," Neurosci Lett, Vol. 216, (1996) pp. 45-48
BK	Spengler et al., "Differential signal transduction by five splice variants of the PACAP receptor," Nature, Vol. 365, (9/9/1993) pp. 170-175

LA-231042.1

<b>EXAMINER:</b>	<b>DATE CONSIDERED:</b>
EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant	

<b>FORM PTO-1449</b>  <b>LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b>  (Use several sheets if necessary)	<b>ATTY. DOCKET NO.</b> 270/175	<b>SERIAL NO.</b> 10/044,722
	<b>APPLICANT:</b> DiCICCO-BLOOM, Emanuel et al.	
	<b>FILING DATE:</b> January 11, 2001	<b>GROUP:</b>



BL	Suh et al., "PACAP is an anti-mitogenic signal in developing cerebral cortex," Nature Neuroscience, Vol. 4, No. 2, (2/2001) pp. 123-124
BM	Takahashi et al., "The leaving or Q fraction of the murine cerebral proliferative epithelium: a general model of neocortical neuronogenesis," J Neurosci., Vol. 16, (10/1/1996) pp. 6183-6196
BN	Tatsuno et al., "Developmental changes of pituitary adenylate cyclase activating polypeptide (PACAP) and its receptor in the rat brain," Peptides, (1994) pp. 55-60
BO	Vaccarino et al., "Changes in cerebral cortex size are governed by fibroblast growth factor during embryogenesis," Nat Neurosci, Vol. 2, No. 3, (3/1999) pp. 246-253
BP	Waschek et al., "Neural tube expression of pituitary adenylate cyclase-activating peptide (PACAP) and receptor: potential role in patterning and neurogenesis," Proc. Natl. Acad. Sci. USA, Vol. 95, (8/1998) pp. 9602-9607

LA-231042.1

<b>EXAMINER:</b>	<b>DATE CONSIDERED:</b>
EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant	